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10/618,546

07/11/2003

Nathan S. Lewis

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07/24/2006

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EXAMINER

LAU, TUNG S

ART UNIT

PAPER NUMBER

2863

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,546

Applicant(s)

LEWIS ET AL.

Examiner

Tung S. Lau

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 55-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 55-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

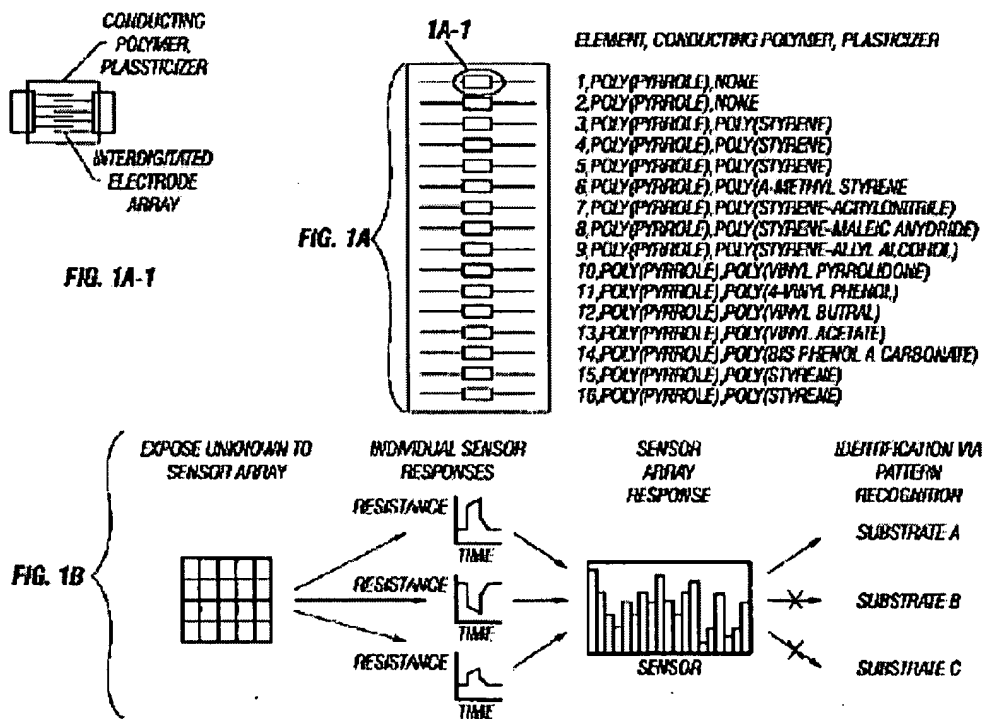
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 2, 4-16, 18-22, 24, 17, 23, 56, 57, 55 and 58 are rejected under 35

U.S.C. 102(e) as being anticipated by Lewis et al. (U.S. Patent Application

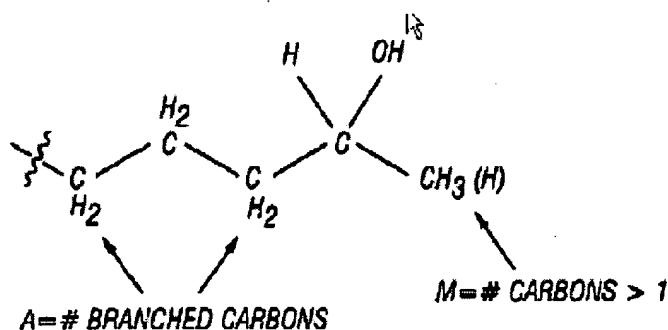
Publication 2004/0042933).



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Regarding claim 1:

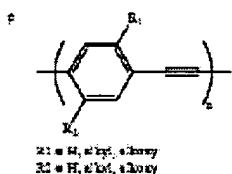
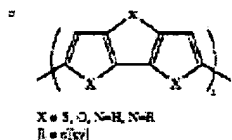
Lewis discloses a method for remote characterization of a gaseous or vapor sample (page 2, section 0023, fig. 1a1, 1b, array sensor), comprising: contacting at least one sensor with a gaseous or vapor sample (page 2, section 0023, fig. 1a-1, array sensor), wherein the sample contains at least one analyte, the at least one sensor (page 2, section 0023, fig. 1a-1, array sensor) comprising a composite having regions of a conductive material and a material compositionally different than the conductive material (page 1, section 0006-0008, section 0011) and wherein the at least one sensor provides a detectable signal when contacted by the at least one analyte (page 1, section 0008-00010); transmitting data corresponding to the detectable signal to a remote location via the internet (page 13, section 0088), fiber-optic cable, and/or an air-wave frequency; analyzing the data received at the remote location (page 13, section 0088), and identifying the at least one analyte present in the gaseous or vapor sample thereby characterizing the sample (page 13, section 0086-0087).

**FIG. 4**

Regarding claim 55:

Lewis discloses a method for remote characterization of a disease in a subject (page 4, section 0041) comprising: contacting at least one sensor with a gaseous or vapor sample obtained from the subject (page 2, section 0023, fig. 1a-1, array sensor), wherein the at least one sensor provides a detectable signal when contacted by an analyte present in the sample (page 2, section 0023, fig. 1a-1, array sensor), the at least one sensor (fig. 1a1, 1b) comprising: regions of a conductive material and regions of a material compositionally different than the conductive material, and wherein the materials provide an electrical path through the regions of conductive material (page 1, section 0006-0008, section 0011) and compositionally different material of the sensor (page 1, section 0006-0008, section 0011), wherein interaction of the analyte with the sensor changes the resistance of the sensor (fig. 1a1, 1b) , electrically measuring a detectable signal of the sensor (fig. 1a1, 1b), transmitting data corresponding to the detectable signal to a remote location, analyzing the data received at the remote location (page 13, section 0088), and identifying the at least one analyte present in the gaseous or vapor sample (page 13, section 0086-0087) thereby characterizing the disease (page 4, section 0041-0042).

TABLE 3-continued



Regarding claim 2, Lewis further discloses plurality of sensors (fig. 1b, array sensor); Regarding claim 3, Lewis further discloses dye-coated fiber optic sensor (page 2-3, section 0026); Regarding claim 4, Lewis further discloses electrically conductive sensor (fig. 1b); Regarding claim 5, Lewis further discloses 5. the electrically conductive sensor comprises regions of a conductive material and a material compositionally different than the conductive material (page 1, section 0006-0008, section 0011), wherein the sensor provides an electrical path through the regions of the conductive material and the regions of the compositionally different material (page 1, section 0006-0008, section 0011), and wherein the conductivity changes upon adsorption with the at least one analyte (fig. 1b); Regarding claim 6, Lewis further discloses at least one region of compositionally different material of one sensor is a different thickness than the region of compositionally different material of at least one other sensor (page 20, section 00162, fig. 1b); Regarding claim 7, Lewis further discloses the compositionally different material is selected from the group consisting of polyanilines (page 6-9,

section 0052) , an emeraldine (page 6, section 0047), salt of polyanilines (page 20, claim 4), polypyrroles (page 5, section 0045), polythiophenes (page 5, section 0046), polyEDOTs (page 5, section 0046), and derivatives thereof (page 5, section 0045-0046); Regarding claim 9, Lewis further discloses sensor is a insulator (page 2, section 0023); Regarding claim 8, Lewis further discloses conductive material is Ag (page 5, section 0042); Regarding claim 10, Lewis further discloses conductive material and non conductive material (page 10, section 0065); Regarding claim 11, Lewis further discloses data is digital representation of the signal (fig. 1b); Regarding claim 12, Lewis further discloses the data is a digital profile representation of the detectable signal from each of the plurality of sensors (fig. 1b); Regarding claim 13, Lewis further discloses sample is an environmental sample (page 2, section 0023); Regarding claim 14, Lewis further discloses sample is an environmental sample is air (page 2, section 0023); Regarding claim 15, Lewis further discloses headspace of a liquid sample (page 4-5, section 0042); Regarding claim 16, Lewis further discloses biological sample (page 4-5, section 0042); Regarding claims 18, 58, Lewis further discloses the biological sample is selected from the group consisting of a breath sample (page 4, section 0041); Regarding claim 19, Lewis further discloses the data is analyzed by comparing the data to a database comprising a data profile from at least one previously-obtained detectable signal from a sample of known composition (page 13, section 0085); Regarding claim 20, Lewis further discloses the analyte in the sample is identified by matching the data to the data profile of a

known composition in the database (page 4, section 0037, page 13, section 0085); Regarding claim 21, Lewis further discloses the data is analyzed by comparing the data to a database containing data profiles from a plurality of detectable signals (page 4, section 0037, page 13, section 0085); Regarding claim 22, Lewis further discloses each data profile in the database is associated with at least one identifier (fig. 1b); Regarding claim 24, Lewis further discloses the analyte is identified by a best match of the data to a data profile in the database and identifying any identifiers associated with the data profile (page 4, section 0037-0039, page 13, section 0085);

Regarding claim 17, the biological sample is selected from the group consisting of a breath sample (page 4, section 0041), a urine sample, a vaginal sample, a feces sample, a tissue sample and a blood sample.

Regarding claim 23, the at least one identifier is selected from the group consisting of location, time, age, sex, disease state, temperature (page 3, section 0027), sample source, sample type, organism, and ethnicity.

Regarding claim 56, the disease is selected from the group consisting of diabetes, liver cirrhosis, halitosis (page 4, section 0041), periodontal disease, pneumonia, vaginitis, uremia, trimethylaminuria, lung cancer, dysgensia, dysosnia, cytinuria, and bacterial vaginosis.

Regarding claim 57, the analyte is an off gas of a member selected from the group consisting of *Prevotella intermedia*, *Fusobacterium nucleatum*, *Porphyromonas gingivalis*, *Porphyromonas endodontalis*, *Prevotella loescheii*,

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Hemophilus parainfluenzae, Stomatococcus mucii, Treponema denticola, Veillonella species, Peptostreptococcus anaerobius, Micros prevotii, Eubacterium limosum, Centipeda periodontii, Selemonad aremidis, Eubacterium species, Bacteriodes species (page 4, section 0041), Fusobacterium periodonticum, Prevotella melaninogenica, Klebsiella pneumoniae, Enterobacter cloacae, Citrobacter species and Stomatococcus mucilaginous.

Response to Arguments

2. Applicant's arguments filed 07/10/2006 have been fully considered but they are not persuasive.

A. Applicant argues that Lewis et al. U.S. Patent Application Publication 2004/0042933 is not a proper 102(e) because by showing the provisional 60/108,915 and 60/108,674 lack the claim invention. The argument is not persuasive because the following reason:

1. The current application claim priority on a DIV 09/596,758, this application has become a patent (6,631,333, filing date Jun 15, 2000), this patent (6,631,333, filing date Jun 15, 2000) which in turn claim CIP of application 09/568,784, provisional application 60/140,027 and 60/133, 318; But the current application (10,618,546) claimed subject matter found in the independent claims (claim 1

and 55) has no support on the CIP (09,568,784, provisional application 60/140,027 or 60/133, 318 see attachment), in particular 09,568,784 provisional application 60/140,027 or 60/133, 318 fail to support the claimed subject matter in claim 1, namely transmitting data corresponding to the detectable signal using fiber-optics cable, air-wave frequency, in page 26 of the 09,568,784 application, talks about the connection using internet (lines 11-15) but not using fiber-optics cable, air-wave frequency (see attachment). Claim 55, namely regions of a conductive material and regions of a material compositionally different than the conductive material, and wherein the materials provide an electrical path through the regions of conductive material and compositionally different material of the sensor, wherein interaction of the analyte with the sensor changes the resistance of the sensor; in page 7-14 of the 09,568,784 application, the applicant discloses the material only being a conducting material and not regions of a conductive material and regions of a material compositionally different than the conductive material, and wherein the materials provide an electrical path through the regions of conductive material and compositionally different material of the sensor, wherein interaction of the analyte with the sensor changes the resistance of the sensor. Therefore, since the application 09/568,784, provisional application 60/140,027 or 60/133, 318 fail to properly support the disclosure in the current application, **the filing date of the current application is June 15, 2000** (filing date of 6,631,333, See MPEP 2133.01). The current prior art rejection using Lewis et al. U.S. Patent

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Application Publication 2004/0042933, having a priority date of Nov. 16, 1999, therefore is a proper 102(e) date.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

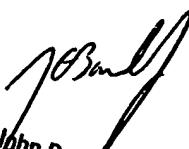
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tung S Lau whose telephone number is 571-272-2274. The examiner can normally be reached on M-F 9-5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on 571-272-2269. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TL


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